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EXTERNAL QUALITY ASSESSMENT

INTERNAL QUALITY CONTROL

REFERENCE MEASUREMENT SERVICES

EDUCATION & TRAINING

Weqas | GLOBAL PROVIDER OF QUALITY IN DIAGNOSTIC MEDICINE

Getting the best out of your EQA data for ISO 15189:2022 compliance

Annette Thomas / Gareth Davies

What do laboratories need from an EQA provider?

JCP Online First, published on March 12, 2014 as 10.1136/jclinpath-2013-201621

Best practice

External quality assessment: best practice

David James,[1] Darren Ames,[2] Berenice Lopez,[3] Rachel Still,[4] Wiliam Simpson,[5] Patrick Twomey[6]

Expectations of EQA Provider

Accreditation status – 17043	• If not accredited, labs should justify why
Clinically relevant Distribution frequency	• Variable across Schemes (EQALM study 2009)* • Where EQA used to assess IVDs, minimum of 6 distributions p.a. (BS EN 14136:2004) • For core tests - monthly
Clinically relevant Range and number of samples	• Evidence of reproducibility • Cover clinically appropriate range • "Blinded" • Commutable materials • Challenging samples
Clinically relevant performance criteria	• Based on clinical outcomes • Based on biological variation

Scheme designed and overseen by appropriately competent professionals	• Clinical Scientist or medically qualified • Independent Scientific or Medical Advisory group. • Statistical expertise
Reporting to Professional body / Regulatory body.	• Mechanism for identification and reporting of Persistent Poor performance issues
Education	• Training • Helpline • Pre analytical • Post Analytical
Post-marketing surveillance	• Alerts manufacturers • Alerts competent authority • Alerts laboratories • Alerts professional bodies

* A Thomas, Accred Qual Assur (2009) 14: 439-444

What does ISO 15189 say?

Definitions

3.32
verification
confirmation of truthfulness, through the provision of objective evidence that specified requirements have been fulfilled

EXAMPLE 1 Confirmation that performance specifications of a measuring system are achieved.

EXAMPLE 2 Confirmation that a target measurement uncertainty can be met.

Note 1 to entry: Verification is the process by which the laboratory confirms that the established performance claims of a measuring system, e.g. trueness, precision, reportable range, can be replicated in the laboratory before human sample examination is performed.

ISO 15189:2022 Clause 6.5: Equipment calibration and metrological traceability

6.5.1 General
The laboratory shall specify calibration and traceability requirements that are sufficient to maintain consistent reporting of examination results. For quantitative methods of a measured analyte, specifications shall include calibration and metrological traceability requirements

6.5.2 Equipment Calibration
The laboratory shall have procedures for the calibration of equipment that directly or indirectly affects examination results. The procedures shall specify:

b) recording of the metrological traceability;

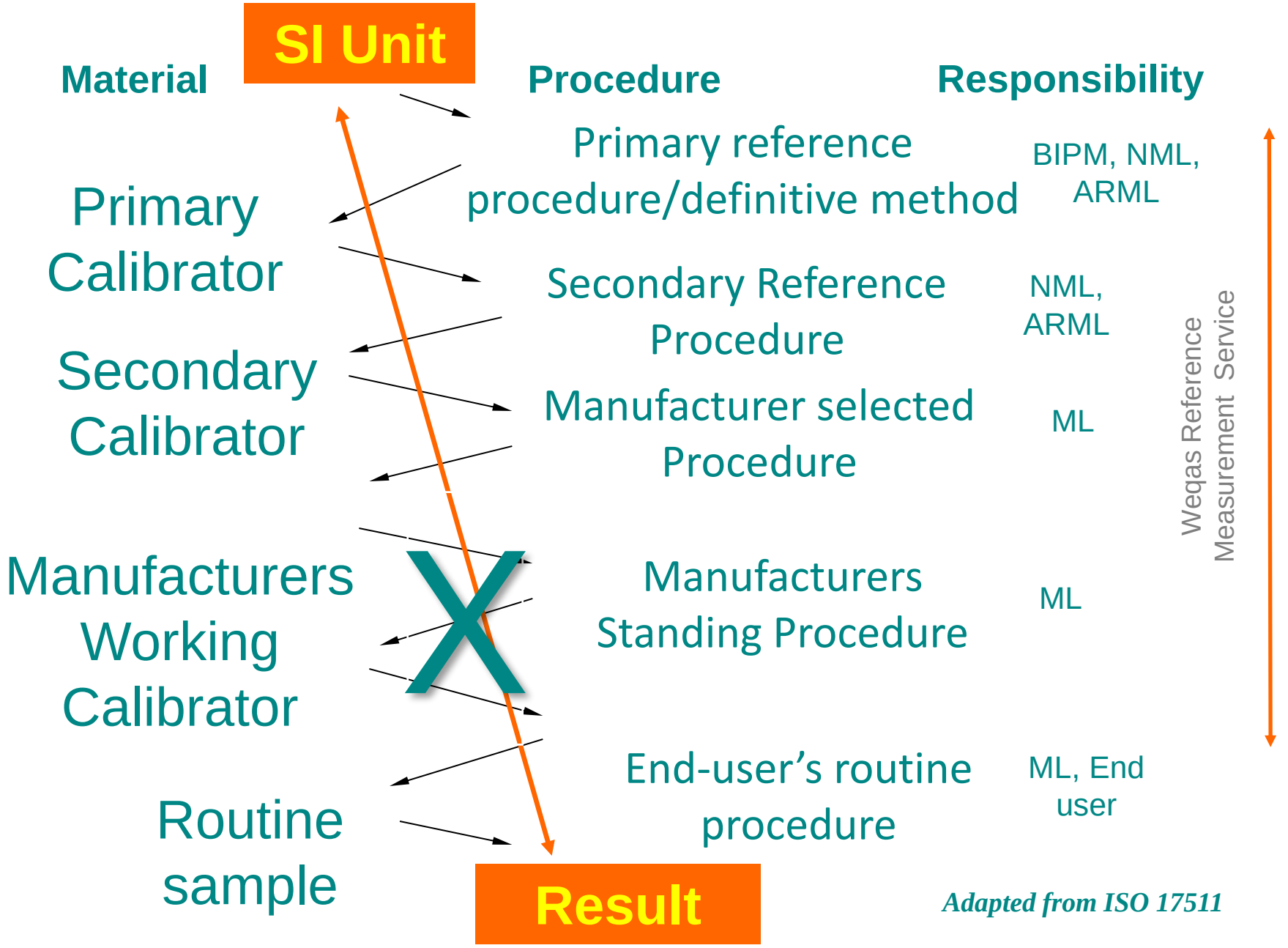
ISO 15189:2022 Clause 6.5: Equipment calibration and metrological traceability

6.5.3 Metrological traceability of measurement results
The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.

b) The laboratory shall ensure that measurement results are traceable to the highest possible level of traceability and to the International System of Units (SI) through:

- calibration provided by a competent laboratory; or
- certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI;

c) Where it is not possible to provide traceability according to 6.5.3 a), other means for providing confidence in the results shall be applied, including but not limited to the following:
— results of reference measurement procedures, specified methods or consensus standards, that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison;



Adapted from ISO 17511

Traceability – Weqas QCRM

- Testosterone and Cortisol Tandem MS standards are assayed quality control material for verification of "in house" prepared calibrators
- Standards prepared and value assigned using the Weqas Reference Measurement Laboratory using traceable material of the highest metrological order.
- Assists with ISO 15189:2022 compliance.

Weqas Testosterone Calibrators CE

Testosterone Targeted Calibrators
Size: 1.0 mL
Lot No: *032418* **Expiry:** *03-2026*

Testosterone Targeted Calibrators

Sample ID	Target Value (nmol/L)	SD	%CV	Expanded Uncertainty
Level 0	0	-	-	-
Level 1*	0.50	-	-	-
Level 2	1.04	0.02	2.00	0.03
Level 3	2.88	0.05	1.85	0.09
Level 4	7.63	0.16	2.09	0.24
Level 5	15.1	0.31	2.06	0.48
Level 6	23.48	0.29	1.24	0.74
Level 7	38.32	0.84	2.20	1.21

Reference Measurement service provided as part of Weqas EQA programmes

Weqas

Flame Atomic Absorption/ Emission Spectrometry

- Sodium, Potassium, Calcium
- Magnesium, Lithium

IFCC Enzymes

- AST, ALT, LDH, GGT

HPLC

- HbA1c **

** Provided by IFCC Ref lab, Netherlands

IDGC-MS & ID-LC-MS/MS

- 17ß-Oestradiol
- Progesterone
- Testosterone
- Cortisol
- Bile Acids
- Creatinine
- Cholesterol
- Glucose
- Urate
- Triglyceride
- HDL *

* Currently provided by CDC lab Rotterdam and WEQAS

Advantages of Reference Measurement Targets

- Traceable to higher order
- Establishes method traceability for the lab – requirement of ISO 15189:2022
- Independent assessment of manufacturer traceability claims.
- Highlights the pitfalls of using the trimmed overall mean as an accuracy target in EQA Schemes
- Overall mean and method mean may not be traceable, may not be stable, may be influenced by large numbers from one manufacturer.
- Useful in the post market vigilance of the IVD - Directive

Traceability From Weqas Reports

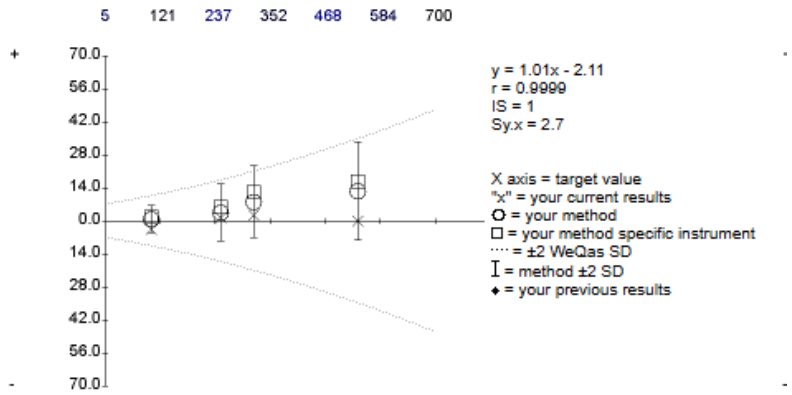
Weqas

Scheme: Serum Chemistry. Distribution Code: SC0425. Distribution Date: 31/03/25. Final. Report Issued: 20/05/25						
Creatinine (µmol/L)		**1**	**2**	**3**	**4**	**Analyte SDI**
Reported Result		251	321	99	538	
Method Corrected Result		251.0	321.0	99.0	538.0	
Enzymatic	Mean	253.1	326.8	103.1	550.5	
	SD	6.1	7.8	2.9	10.6	
	Number	64	63	61	62	
	Uncert.	0.77	0.98	0.37	1.34	
Cobas C Module	Mean	255.6	330.9	104.1	555.0	
	SD	4.4	4.8	1.8	7.5	
	Number	43	41	40	42	
	Uncert.	0.67	0.75	0.28	1.16	
Overall	Mean	249.8	323.1	101.6	541.4	
	SD	7.9	10.0	3.6	15.6	
	Number	123	121	122	122	
	Uncert.	0.71	0.91	0.33	1.42	
Reference Values ID-GCMS		249.9	318.7	102.6	538.1	
Ref. Value Uncertainty		2.16	2.76	0.89	4.66	
Non-scoring Reference Values						
WeQas SD		8.8	10.8	5.4	17.8	
SDI		**0.13**	**0.22**	**-0.67**	**-0.01**	**0.25**

Sigma Metrics			
Critical Level 1: 75 µmol/L			
Minimum Acceptable score	1.67	Critical Level 1 Sigma score	2.0
MAPS Allowable TE	9.5%		
MAPS Allowable bias %	5.0%	Lab |bias| %	2.1%
MAPS Allowable CV %	2.7%	Lab CV %	3.6%

Please note: Linear regression uses CF corrected data.

This Distribution *SC0425*



- Reference measurement values shown on report (and reference value uncertainty).
- Full traceability chain to SI units available.
- Lab results compared directly to reference values
- SDI scores, Sigma scores and bias plot based on reference values

ISO 15189:2022 Clause 6.5: Equipment calibration and metrological traceability

6.5.2 Equipment Calibration

The laboratory shall have procedures for the calibration of equipment that directly or indirectly affects examination results. The procedures shall specify:

c) verification of the required measurement accuracy and the functioning of the measuring system at specified intervals;

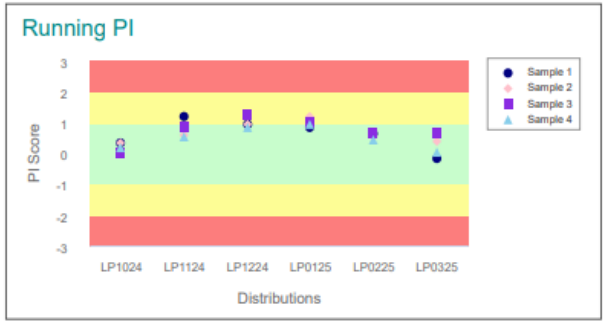
Assessment of Accuracy (trueness & imprecision)

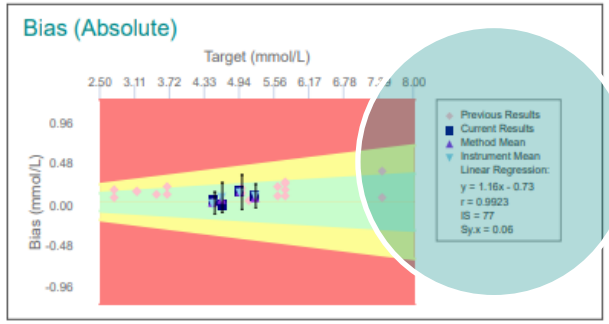
Weqas

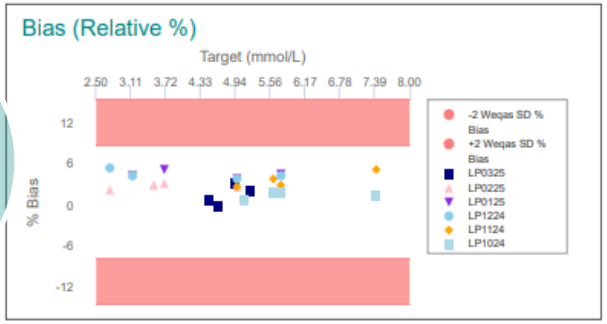
Cholesterol mmol/L							
	Your reported result (mmol/L)		Method: Chol Oxidase (CDC)	Instrument Model: cobas c 501	Overall	Scoring Reference Value	Non-Scoring Reference Value
Sample 1	4.6	Mean	4.668	4.681	4.662	4.63	4.56
		SD	0.074	0.085	0.078		
		Uncertainty	0.0111	0.0275	0.0102	0.007	n/a
		n	69	15	92		
Sample 2	5.3	Mean	5.281	5.289	5.287	5.22	5.14
		SD	0.092	0.069	0.093		
		Uncertainty	0.0138	0.0222	0.0121	0.007	n/a
		n	69	15	92		
Sample 3	5.1	Mean	5.098	5.085	5.101	4.97	5.04
		SD	0.093	0.103	0.087		
		Uncertainty	0.0140	0.0333	0.0114	0.007	n/a
		n	69	15	92		
Sample 4	4.5	Mean	4.485	4.483	4.485	4.49	4.44
		SD	0.078	0.065	0.084		
		Uncertainty	0.0118	0.0211	0.0110	0	n/a
		n	69	15	92		

Scoring

Sample	1	2	3	4	Overall Performance
Target: (Reference Value)	4.63	5.22	4.97	4.49	
Weqas TAE	0.384	0.433	0.413	0.373	
PI	-0.16	0.37	0.63	0.05	Good

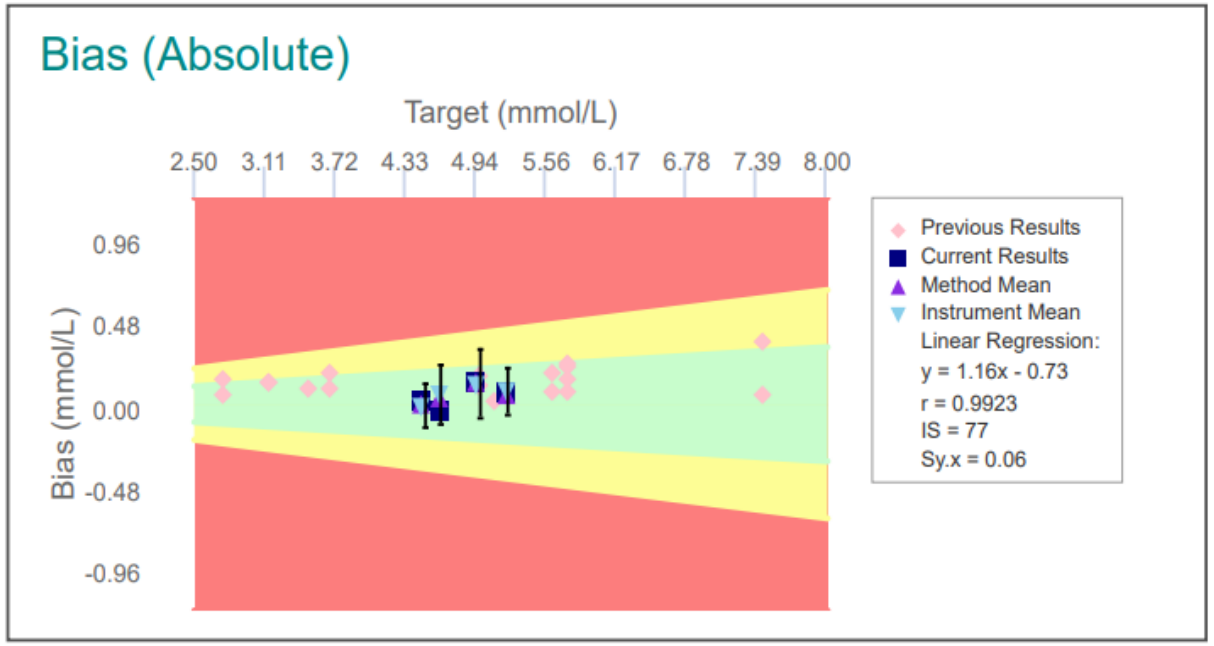






From the linear regression analysis equation, y=mx+c, the trueness (bias) can be calculated for any concentration.

Assessment of Accuracy (trueness & imprecision)



From the linear regression analysis equation, y=mx+c, the trueness (bias) can be calculated for any concentration.

Use Cholesterol 5.0 mmol/L.

From report: y = 1.16x – 0.73

when x=5 then y= 1.16*5 -0.73
y = 5.07

Bias = (y-x)/x*100 = (5.07-5.0)/5.0*100 = 1.4%

Imprecision (CV) = Sy.x/x = 0.06/5.0*100 = 1.2%

ISO 15189:2022 Clause 7: Process Requirements

7.3.4 Evaluation of measurement uncertainty (MU)

a) The MU of measured quantity values shall be evaluated and maintained for its intended use, where relevant. The MU shall be compared against performance specifications and documented.
b) MU evaluations shall be regularly reviewed.
c) For examination procedures where evaluation of MU is not possible or relevant, the rationale for exclusion from MU estimation shall be documented.
d) MU information shall be made available to laboratory users on request.
e) When users have inquiries on MU, the laboratory's response shall take into account other sources of uncertainty, such as, but not limited to biological variation.
f) If the qualitative result of an examination relies on a test which produces quantitative output data and is specified as positive or negative, based on a threshold, MU in the output quantity shall be estimated using representative positive and negative samples.
g) For examinations with qualitative results, MU in intermediate measurement steps or IQC results which produce quantitative data should also be considered for key (high risk) parts of the process.
h) MU should be taken into consideration when performing verification or validation of a method, when relevant.

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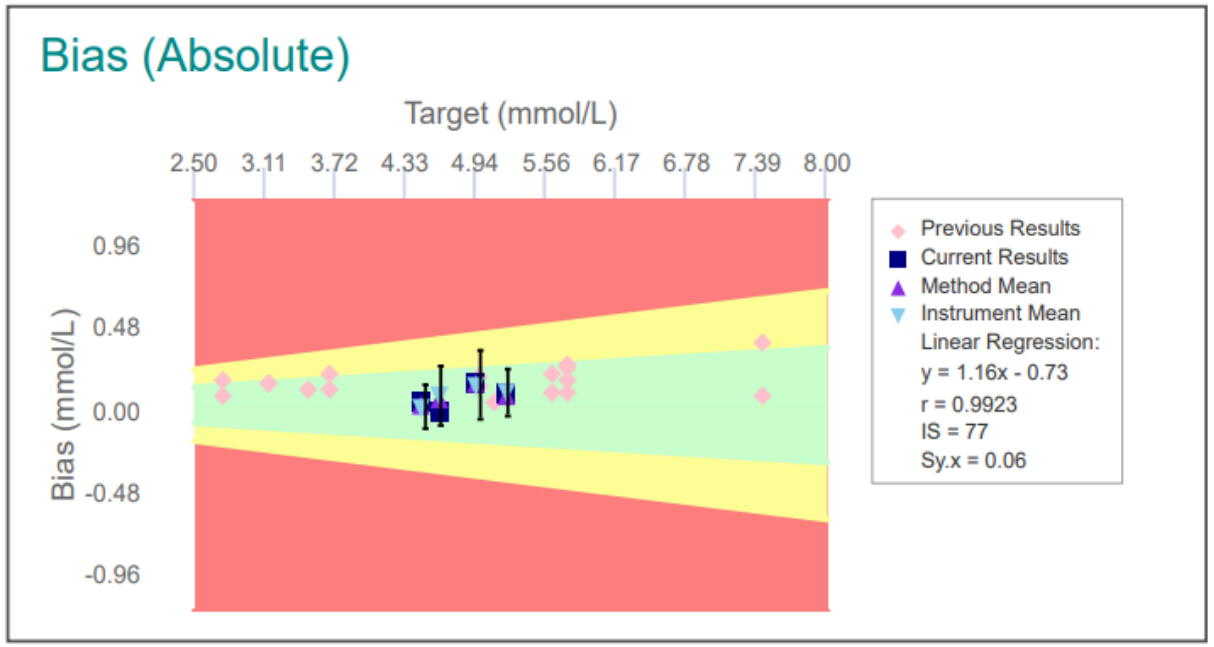
Uncertainty – Laboratory Within Run Imprecision



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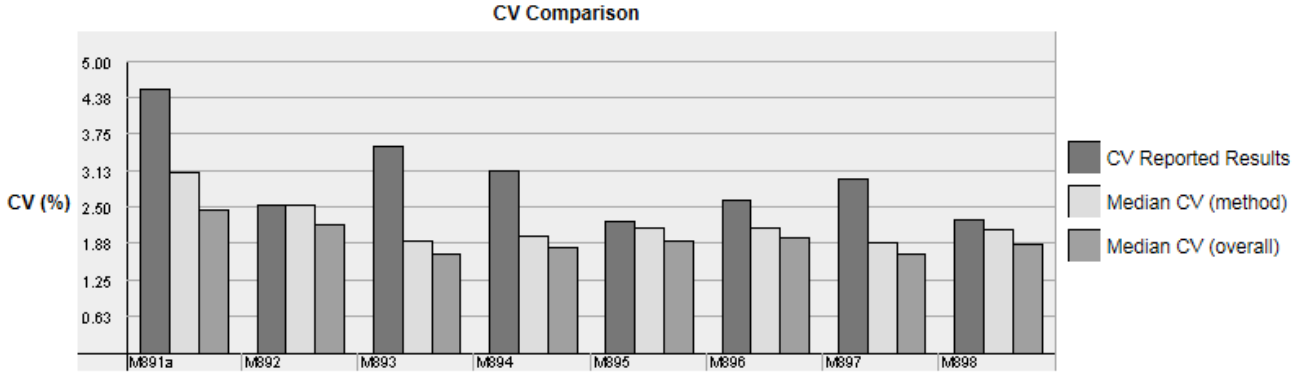
Laboratory Within Run imprecision

Imprecision (CV) = Sy.x/x = 0.06/5.0*100 = 1.2%

Uncertainty From EQA Data

Analyte: Creatinine (µmol/L)

Method: **Jaffe - IDMS**	**M891a**	**M892**	**M893**	**M894**	**M895**	**M896**	**M897**	**M898**
Section Stats								
Mean reported results	64.5	133.6	206.8	276.7	346.9	420.1	490.6	558.4
SD reported results	2.9	3.4	7.3	8.6	7.8	11.0	14.7	12.7
CV(%) reported results	4.51	2.52	3.52	3.10	2.25	2.61	2.99	2.27
Number of results	5	5	4	3	5	5	5	6
Method Result Stats								
Mean method mean	67.7	139.3	213.3	286.6	357.4	428.9	498.4	570.0
Median CV	3.08	2.52	1.91	2.00	2.14	2.14	1.88	2.11
Overall Result Stats								
Median CV	2.44	2.19	1.69	1.81	1.92	1.97	1.70	1.85



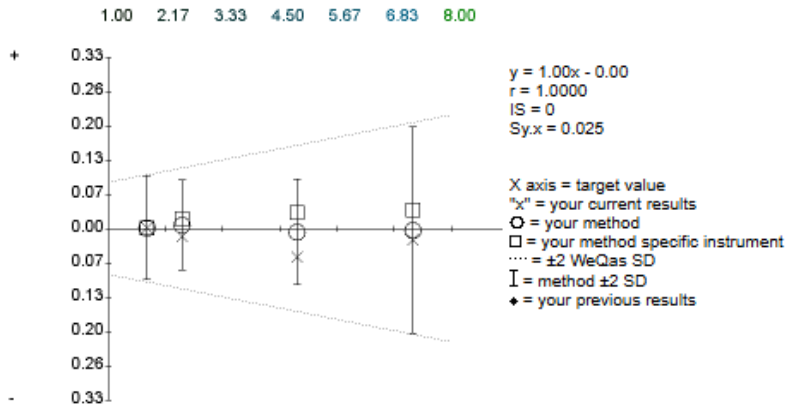
Between batch CV% provided on End of Batch reports (12 month review)
Pool M891a - CV% of reported results: 4.51%
Top-down approach – CV% is method uncertainty (relative standard uncertainty)

Method Linearity from Weqas

Scheme: Serum Chemistry. Distribution Code: SC0423. Distribution Date: 3/04/23. Final. Report Issued: 18/05/23						
Potassium (mmol/l)		**1**	**2**	**3**	**4**	**Analyte SDI**
Reported Result		1.80	4.80	2.50	7.20	
Method Corrected Result		1.800	4.800	2.500	7.200	
Indirect ISE	Mean	1.800	4.849	2.523	7.219	
	SD	0.050	0.051	0.043	0.099	
	Number	122	110	112	117	
	Uncert.	0.0045	0.0048	0.0041	0.0092	
Cobas C Module	Mean	1.801	4.886	2.536	7.258	
	SD	0.007	0.058	0.047	0.072	
	Number	55	69	63	64	
	Uncert.	0.0009	0.0070	0.0060	0.0090	
Overall	Mean	1.799	4.856	2.516	7.222	
	SD	0.051	0.067	0.050	0.101	
	Number	123	124	119	120	
	Uncert.	0.0046	0.0060	0.0046	0.0092	
Reference Values						
Ref. Value Uncertainty						
Non-scoring Reference Values						
WeQas SD		0.052	0.080	0.058	0.102	
SDI		**0.00**	**-0.61**	**-0.39**	**-0.18**	

Please note: Linear regression uses CF corrected data.

This Distribution *SC0423*



- Linear series of 8 pools distributed for most routine chemistry programmes
- Linear series cover wide analytical and pathological range
- Chemistry QCRM linearity panel available as a range of up to 8 samples and are suitable for ISO 15189:2022 method verification

Weqas

Serum Chemistry QCRM

CE

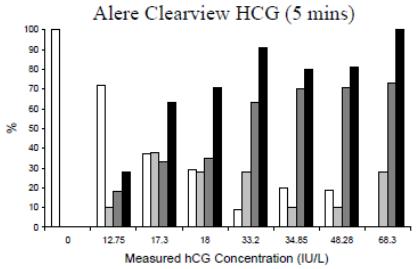
Serum Chemistry Quality Control Reference Material
Size: 3.5mL
Lot No: 080118/93 **Exp.: Jan-2020**

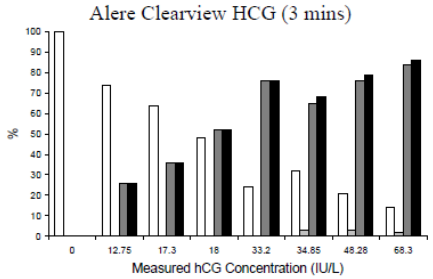
Creatinine

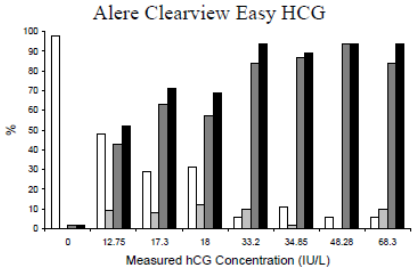
Pool	ID-GCMS Target Value (µmol/L)	Expanded Uncertainty
932	110.98	1.38
934	262.15	3.25
936	414.37	5.14
938	559.71	6.94

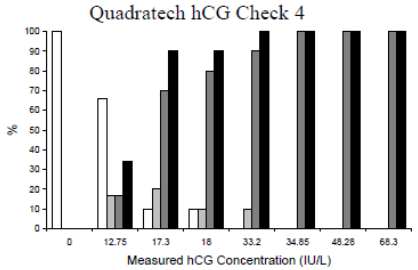
Weqas Specificity and Sensitivity Studies

Pregnancy testing









Bile Acids

Results

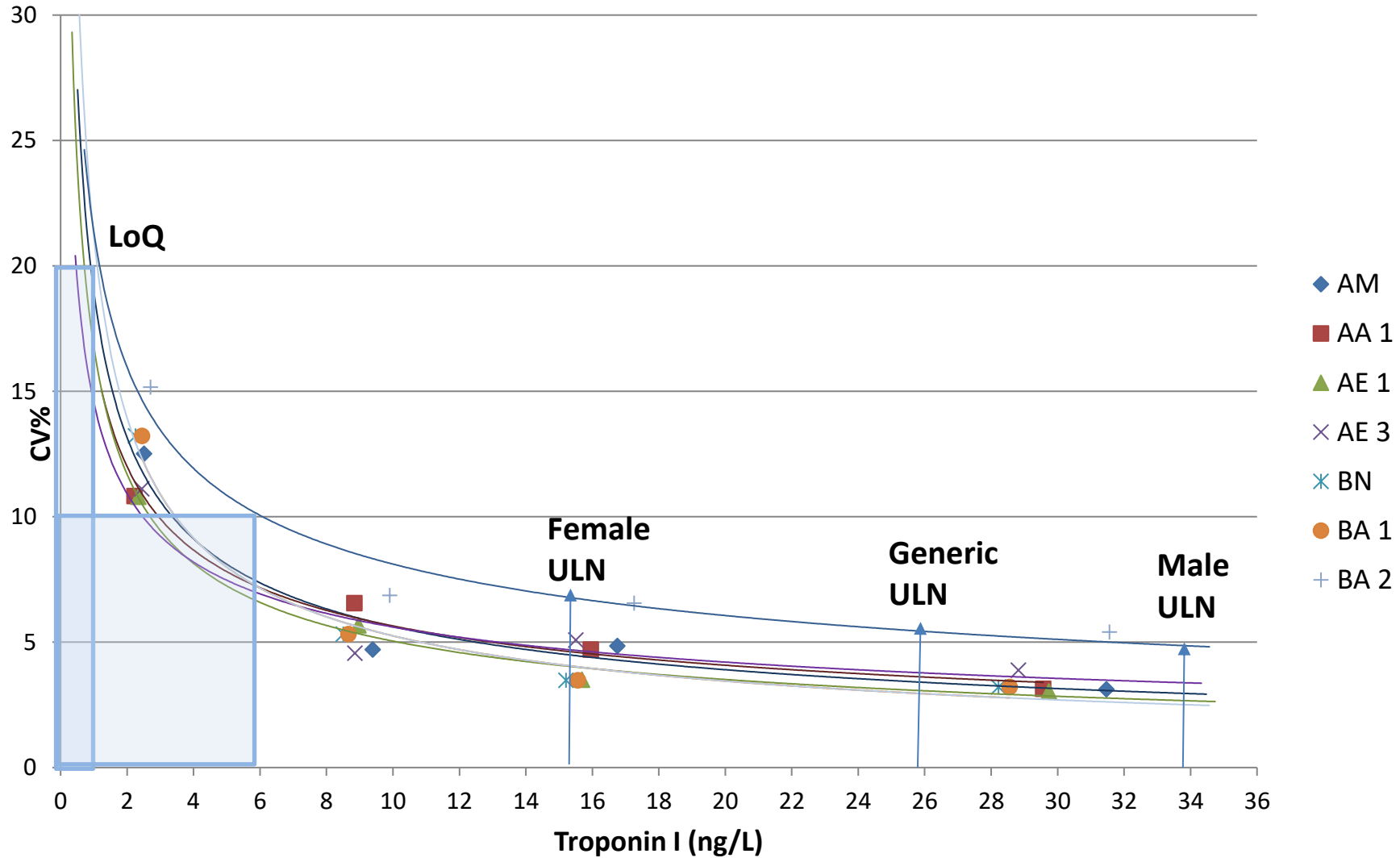
Table 3 shows the summary data from the distributed recovery samples. The predominant group is represented by the Enz-Thio-NADH method (86% of scheme participants), with the Enz-Formazan group representing 5% of scheme participants and the Sentinel Enz-Formazan group 9% of scheme participants.

Table 3 Bile Acid Recovery Experiment: comparison with ID-GCMS Targets

POOL ID	CHOLIC ACID				DEOXYCHOLIC			
	µmol/L				µmol/L			
	ID-GCMS Target				ID-GCMS Target			
POOL A (sample 4)	103.18							
POOL B (sample 5)					108.78			
POOL C (sample 6)								
POOL D (sample 7)								
Returned results	mean	SD	n	% recovery	mean	SD	n	% recovery
overall	101.18	7.54	111	98.06	137.80	15.87	110	126.68
Enz-Thio-NADH	99.89	6.59	95	96.81	141.27	15.64	94	129.87
Enz-Formazan	89.5	1.50	5	86.74	137.00	15.00	2	125.94
Enz-Formazan (Sentinel)	112.41	4.90	15	108.95	119.42	5.08	15	109.78

POOL ID	URSODEOXYCHOLIC				CHENODEOXYCHOLIC			
	µmol/L				µmol/L			
	Spiked Target				ID-GCMS Target			
POOL A (sample 4)								
POOL B (sample 5)								
POOL C (sample 6)					77.14			
POOL D (sample 7)	100							
Returned results	mean	SD	n	% recovery	mean	SD	n	% recovery
overall	57.81	8.44	107	57.81	56.05	7.30	107	72.66
Enz-Thio-NADH	56.00	4.44	98	56.00	54.25	4.61	95	70.32
Enz-Formazan	51.50	0.5	2	51.50	51.00	2.00	2	66.11
Enz-Formazan (Sentinel)	90.47	3.33	15	90.47	77.05	2.88	12	99.88

High sensitivity Troponin



Method interference Testing

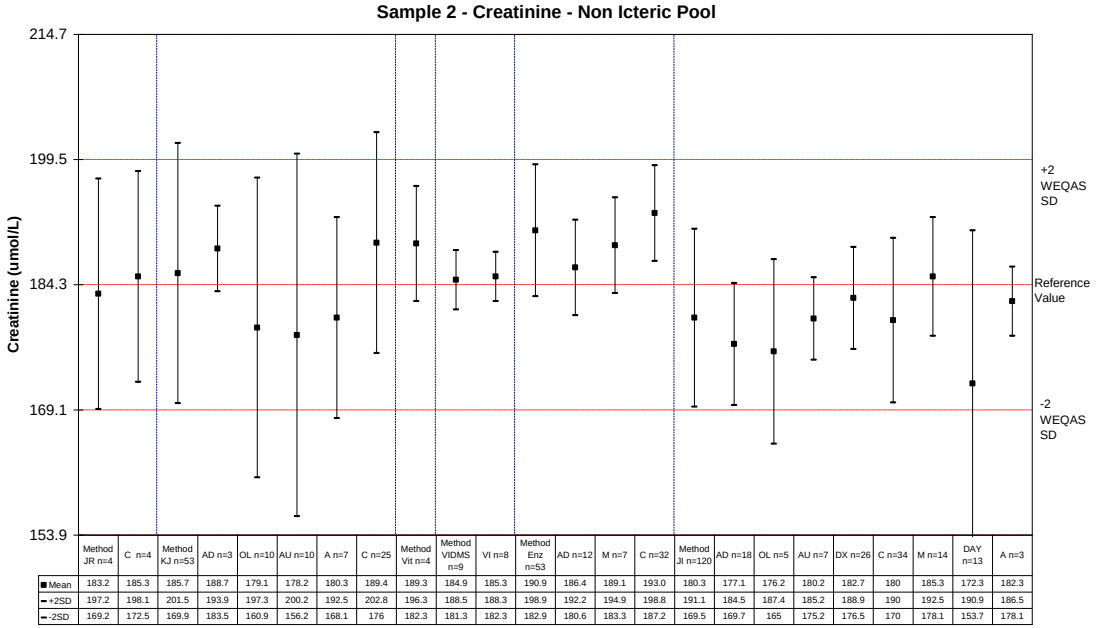
Pre analytical, analytical and Post analytical exercises.

Serum Chemistry, HIL Indices Programmes, questionnaires sent out as part of Programme repertoire re: pre analytical sample handling, adjustded calcium equations.

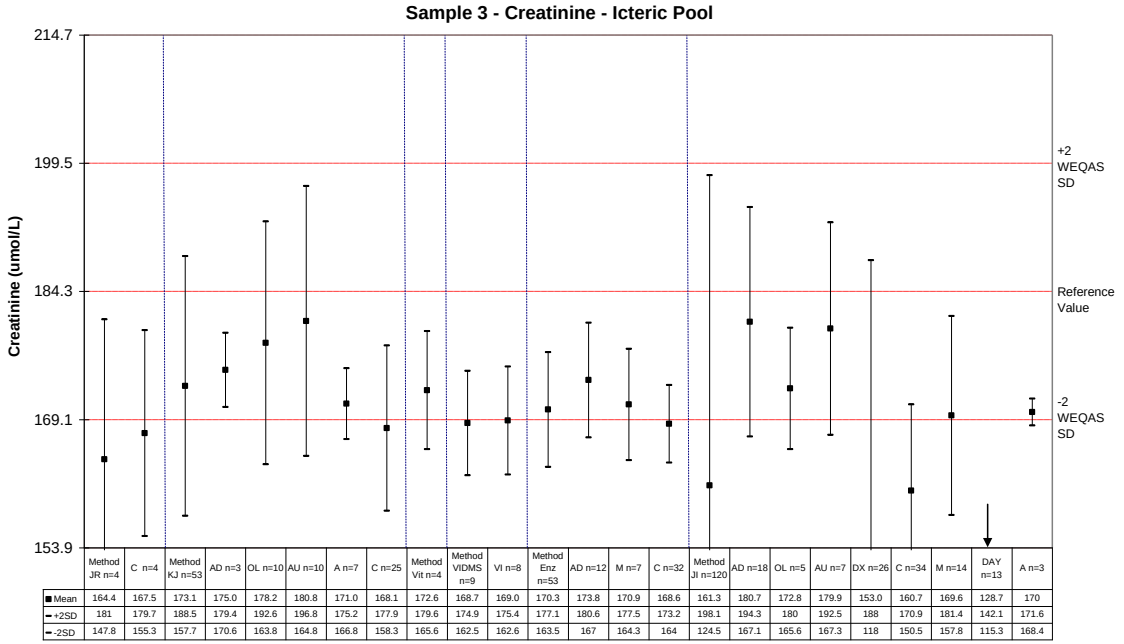
Interference Studies e.g. Bilirubin effect on Salicylate & Paracetamol, HIL indices studies on Serum Chemistry and Endocrine programmes

Post analytical interpretation / cases provided with Programmes e.g. Porphyrin interpretation cases, Macroprolactin samples, EQA for calculated parameters, pre-eclampsia risk outcomes.

Weqas Interference Reports



	Method JR n=4	C n=4	Method KJ n=53	AD n=3	OL n=10	AU n=10	A n=7	C n=25	Method Vit n=4	Method VIDMS n=9	VI n=8	Method Enz n=53	AD n=12	M n=7	C n=32	Method JI n=120	AD n=18	OL n=5	AU n=7	DX n=26	C n=34	M n=14	DAY n=13	A n=3
Mean	183.2	185.3	185.7	188.7	179.1	178.2	180.3	189.4	189.3	184.9	185.3	190.9	186.4	189.1	193.0	180.3	177.1	176.2	180.2	182.7	180	185.3	172.3	182.3
+2SD	197.2	198.1	201.5	193.9	197.3	200.2	192.5	202.8	196.3	188.5	188.3	198.9	192.2	194.9	198.8	191.1	184.5	187.4	185.2	188.9	190	192.5	190.9	186.5
-2SD	169.2	172.5	169.9	183.5	160.9	156.2	168.1	176	182.3	181.3	182.3	182.9	180.6	183.3	187.2	169.5	169.7	165	175.2	176.5	170	178.1	153.7	178.1



	Method JR n=4	C n=4	Method KJ n=53	AD n=3	OL n=10	AU n=10	A n=7	C n=25	Method Vit n=4	Method VIDMS n=9	VI n=8	Method Enz n=53	AD n=12	M n=7	C n=32	Method JI n=120	AD n=18	OL n=5	AU n=7	DX n=26	C n=34	M n=14	DAY n=13	A n=3
Mean	164.4	167.5	173.1	175.0	178.2	180.8	171.0	168.1	172.6	168.7	169.0	170.3	173.8	170.9	168.6	161.3	180.7	172.8	179.9	153.0	160.7	169.6	128.7	170
+2SD	181	179.7	188.5	179.4	192.6	196.8	175.2	177.9	179.6	174.9	175.4	177.1	180.6	177.5	173.2	198.1	194.3	180	192.5	188	170.9	181.4	142.1	171.6
-2SD	147.8	155.3	157.7	170.6	163.8	164.8	166.8	158.3	165.6	162.5	162.6	163.5	167	164.3	164	124.5	167.1	165.6	167.3	118	150.5	157.8	115.3	168.4

The reference value (ID-GCMS) was 184.3 µmol/L for sample 2 and 184.4 µmol/L for sample 3

ISO 15189:2022 7.3.7.3 External quality assessment (EQA)

a) The laboratory shall monitor its performance of examination methods, by comparison with results of other laboratories. This includes participation in EQA programmes appropriate to the examinations and interpretation of examination results, including POCT examination methods.
b) The laboratory shall establish a procedure for EQA enrolment, participation and performance for examination methods used, where such programmes are available.
c) EQA samples shall be processed by personnel who routinely perform pre-examination, examination, and post-examination procedures.
d) The EQA programme(s) selected by the laboratory shall, to the extent possible:
1) have the effect of checking pre-examination, examination, and post-examination processes;
2) provide samples that mimic patient samples for clinically relevant challenges;
3) fulfil ISO/IEC 17043 requirements.

Clinically relevant samples at diagnostic cut-points

Clinically Relevant Range and number of samples

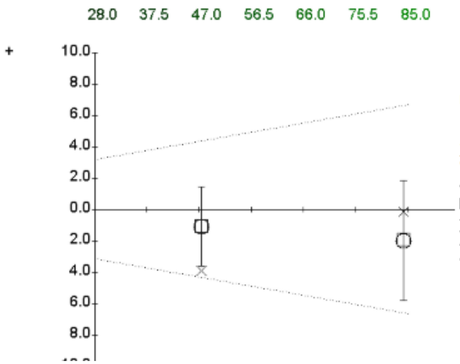
- Sample numbers for each scheme assessed on an individual scheme basis e.g. Serum Chemistry (linear panel of 4) and POCT Glucose / Urinalysis (1 sample per distribution).
- Appropriate sample matrices, endogenous, commutable, challenging, linear panels to assess method linearity, specificity and sensitivity
- Weqas covers pathological and analytical ranges. Careful selection of endogenous material to ensure range is covered, selected sources of material e.g. real patient material, some samples spiked to achieve full range and/or provide linear panels
- Cover critical “diagnostic cut points” e.g. high sensitivity Troponin, urine hCG, HbA1c, POCT CRP
- For Qualitative schemes we provide an appropriate number positive and negative pools, underpinned with known quantitative concentrations.

Weqas Reports - Clinically relevant samples

Scheme: HbA1c. Distribution Code: HC0325. Distribution Date: 25/03/25. Final. Report Issued: 12/05/25				
HbA1c IFCC (mmol/mol)		**1**	**2**	**Analyte SDI**
Reported Result		84.0	43.0	
Method Corrected Result		84.00	43.00	
POCT Boronate Affinity	Mean	81.92	46.24	
	SD	2.17	1.43	
	Number	201	206	
	Uncert.	0.191	0.124	
Afinion 2	Mean	81.99	46.29	
	SD	2.09	1.32	
	Number	158	159	
	Uncert.	0.208	0.131	
Overall	Mean	81.48	46.74	
	SD	3.27	2.04	
	Number	516	531	
	Uncert.	0.180	0.111	
Reference Values IFCC		84.20	47.50	
Ref. Value Uncertainty		1.300	1.000	
Non-scoring Reference Values				
WeQas SD		3.67	2.46	
SDI		**-0.05**	**-1.83**	**0.94**
Sigma Metrics				
Sigma score not calculated: *Insufficient results submitted*				

Please note: Linear regression uses CF corrected data.

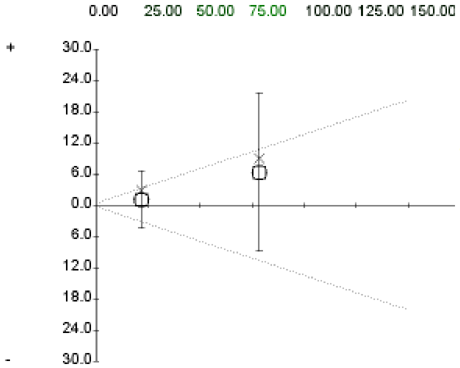
This Distribution *HC0325*



Scheme: PoCT CRP. Distribution Code: R7. Distribution Date: 17/04/18. Final. Report Issued: 4/05/18				
CRP (mg/L)		**1**	**2**	**Analyte SDI**
Reported Result		88.00	25.00	
Method Corrected Result		88.000	25.000	
QuikRead go	Mean	85.156	23.000	
	SD	8.054	2.875	
	Number	7	8	
	Uncert.	3.8053	1.2704	
QuikRead go	Mean	85.156	23.000	
	SD	8.054	2.875	
	Number	7	8	
	Uncert.	3.8053	1.2704	
Overall	Mean	78.617	22.000	
	SD	6.204	1.574	
	Number	35	36	
	Uncert.	1.3108	0.3279	
Reference Values				
Ref. Value Uncertainty				
Non-scoring Reference Values				
WeQas SD		5.703	1.740	
SDI		**0.50**	**1.15**	**0.82**

Please note: Linear regression uses CF corrected data.

This Distribution *R7*



SureScreen	SureScreen hCG GHCGC	Negative	Negative	Negative	Negative	3	1	1	0	1.67
SureScreen	SureScreen hCG GHCGC	Positive	Positive	Positive	Negative	0	0	0	0	0.00
SureScreen	SureScreen hCG GHCGC	Positive	Positive	Positive	Negative	0	0	0	0	0.00
SureScreen	SureScreen hCG GHCGC	Negative	Negative	Negative	Negative	3	1	1	0	1.67
SureScreen	SureScreen hCG GHCGC	Negative	Positive	Positive	Negative	3	0	0	0	1.00
SureScreen	SureScreen hCG GHCGC	Positive	Positive	Positive	Negative	0	0	0	0	0.00
SureScreen	SureScreen hCG GHCGC	Positive	Positive	Positive	Negative	0	0	0	0	0.00
SureScreen	SureScreen hCG GHCGC	Positive	Positive	Positive	Negative	0	0	0	0	0.00
SureScreen	SureScreen hCG GHCGC	Positive	Positive	Positive	Negative	0	0	0	0	0.00
SureScreen	SureScreen hCG GHCGC	Positive	Positive	Positive	Negative	0	0	0	0	0.00
SureScreen	SureScreen hCG GHCGC	Positive	Positive	Positive	Negative	0	0	0	0	0.00
SureScreen	SureScreen hCG GHCGC	Positive	Positive	Positive	Negative	0	0	0	0	0.00
SureScreen	SureScreen Midstream GHCGMS	Positive	Positive	Positive	Negative	0	0	0	0	0.00
Veda.Lab	BabyCheck-1	Positive	Positive	Positive	Negative	0	0	0	0	0.00
Veda.Lab	BabyCheck-1	Positive	Positive	Positive	Negative	0	0	0	0	0.00
Veda.Lab	BabyCheck-1									
Veda.Lab	BabyCheck-1	Positive	Positive	Positive	Negative	0	0	0	0	0.00
VISITECT Pregnancy	VISITECT Pregnancy	Positive	Positive	Positive	Negative	0	0	0	0	0.00
Interpretation		**Positive**	**Equivocal, further investigation**	**Equivocal, further investigation**	**Negative**					
Spiked Value		**Approximately 35 IU/L**	**Approximately 22 IU/L**	**Approximately 13 IU/L**	**Approximately 4 IU/L**					

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EXTERNAL QUALITY ASSESSMENT

INTERNAL QUALITY CONTROL

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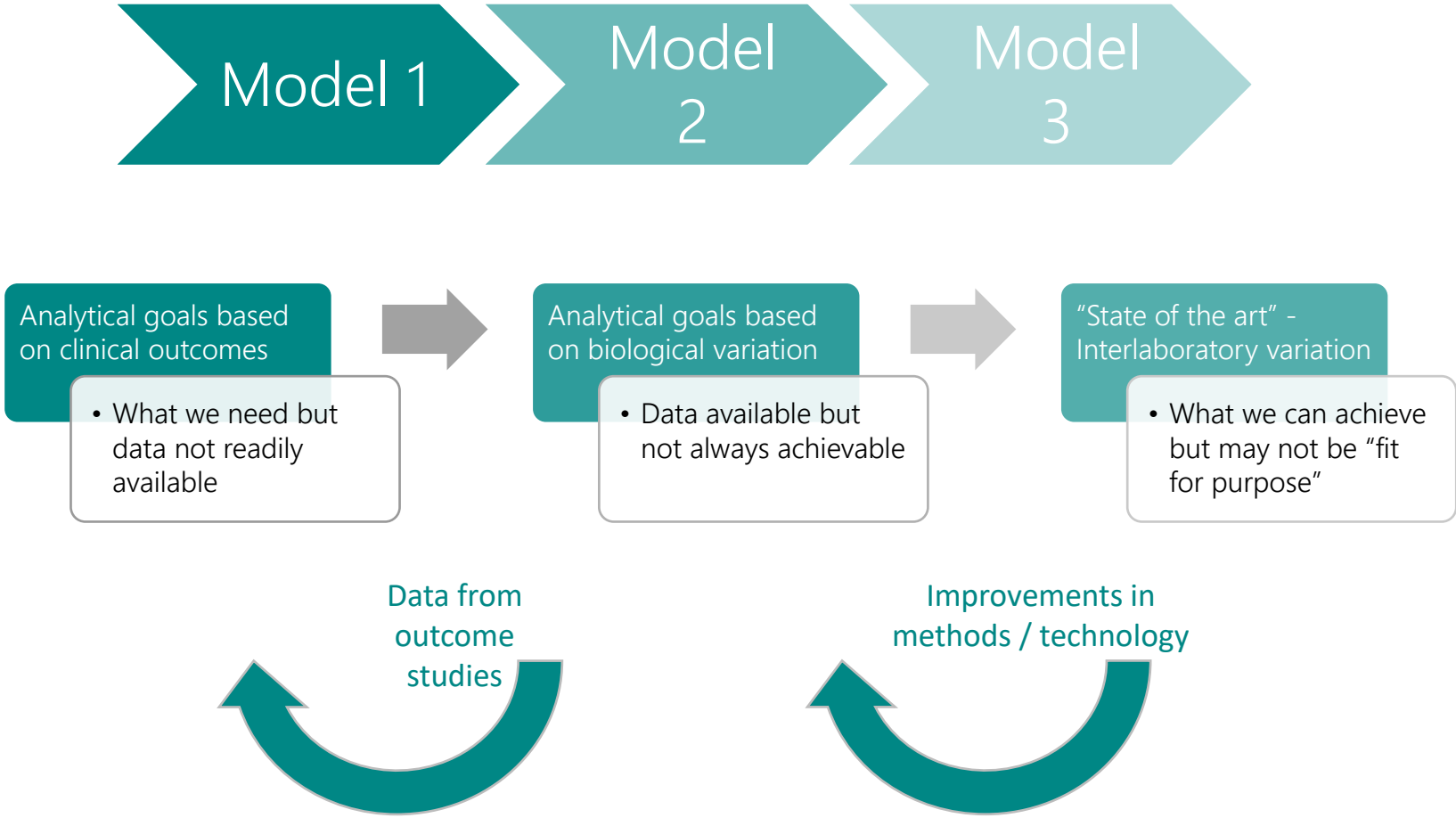
Analytical performance specifications (APS) - are we providing clinically appropriate APS for External Quality Assessment?

Annette Thomas

Director

www.weqas.com

Clinically Relevant Performance Specification



Method

Laboratory method performance data from Weqas in the UK was collected over the last five years across a wide clinical concentration for the common analytes in Clinical Biochemistry. The data covered 60 distributions using up to 240 samples, assayed by up to 200 laboratories using a range of analysers. Precision profiles were calculated for each sample for the overall data and for each of the major methods and analysers used for that analyte. The minimum number of data points for each analyser for each sample distribution was set at 5. The interlaboratory variation was represented as Standard Deviation, (SD), and/or Coefficient of variation, (CV), and plotted against analyte concentration. For certain analytes the data was also assessed according to whether the analyte was used for laboratory diagnosis or POCT monitoring.

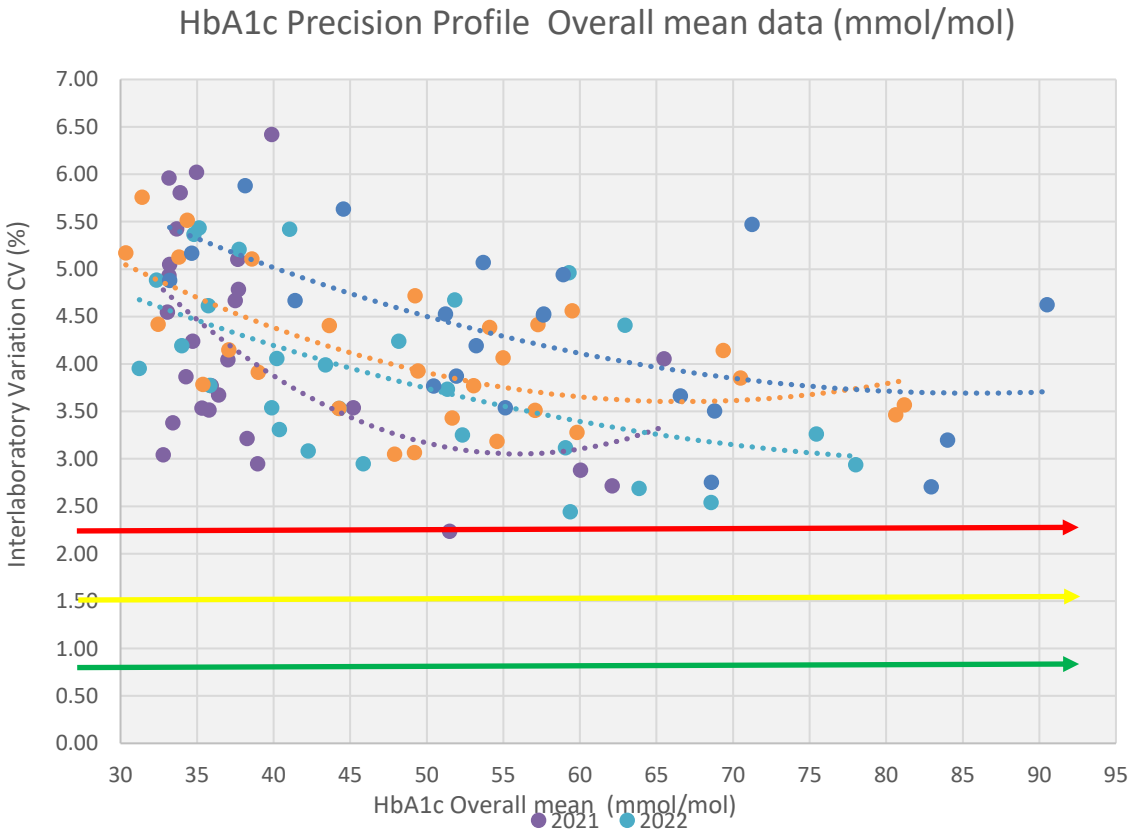
HbA1c Precision Profile

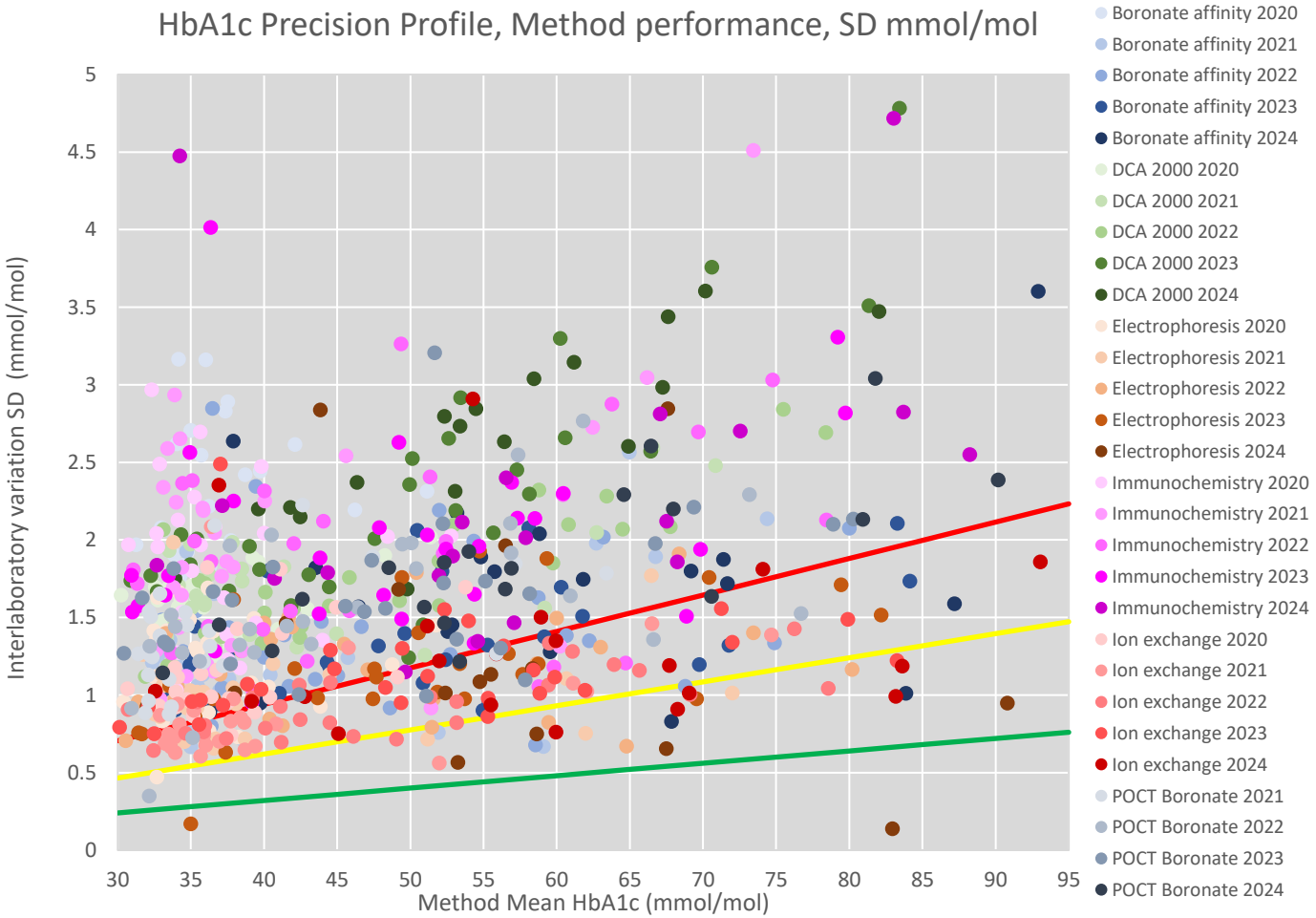
Overall data also includes affects of bias. Data includes laboratory and POCT methods

Can we use universal APS based on biological variation? – NO

Should we use different APS for laboratory and POCT methods? - **YES**

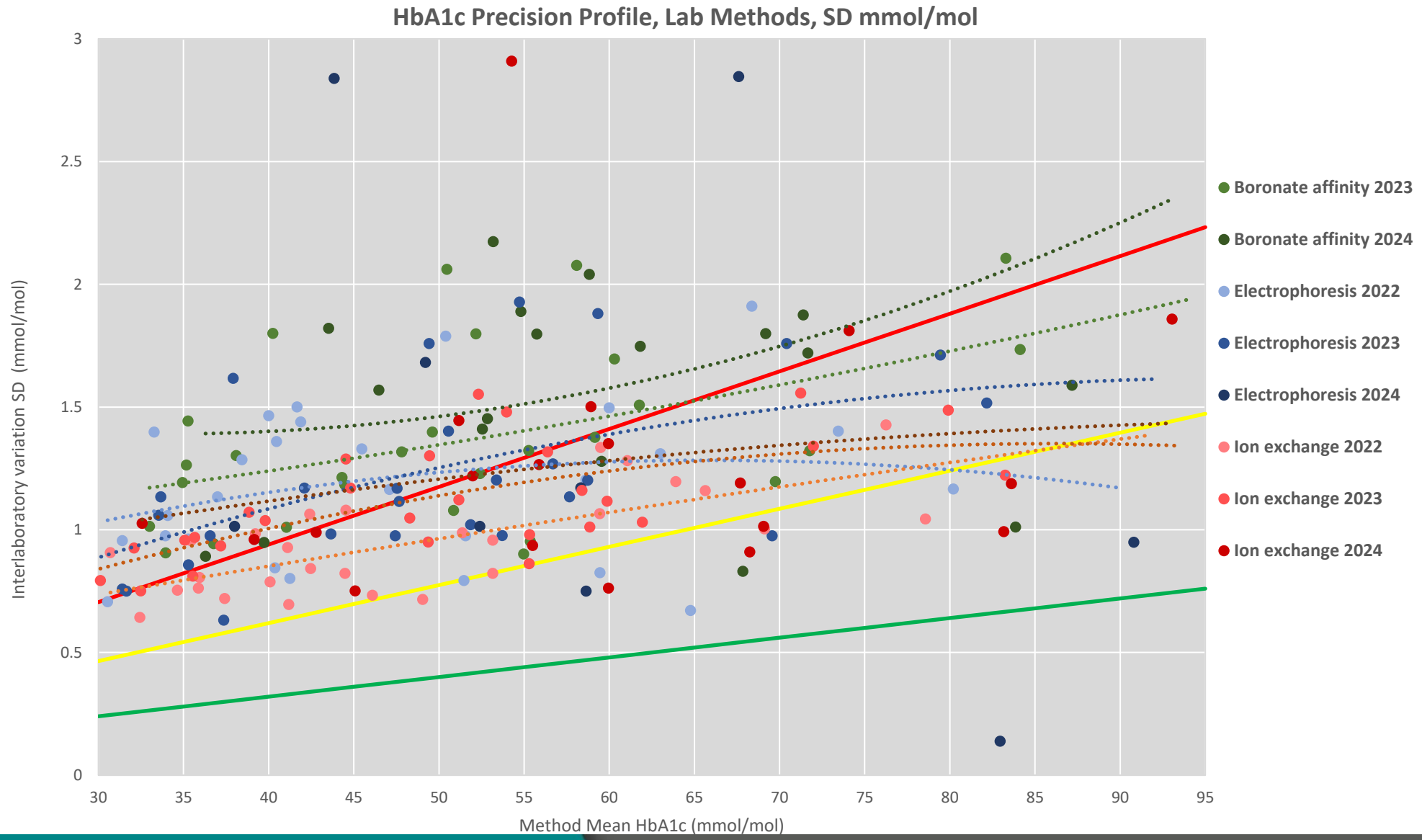
Some laboratory electrophoresis and Ion exchange methods can achieve **Minimum**



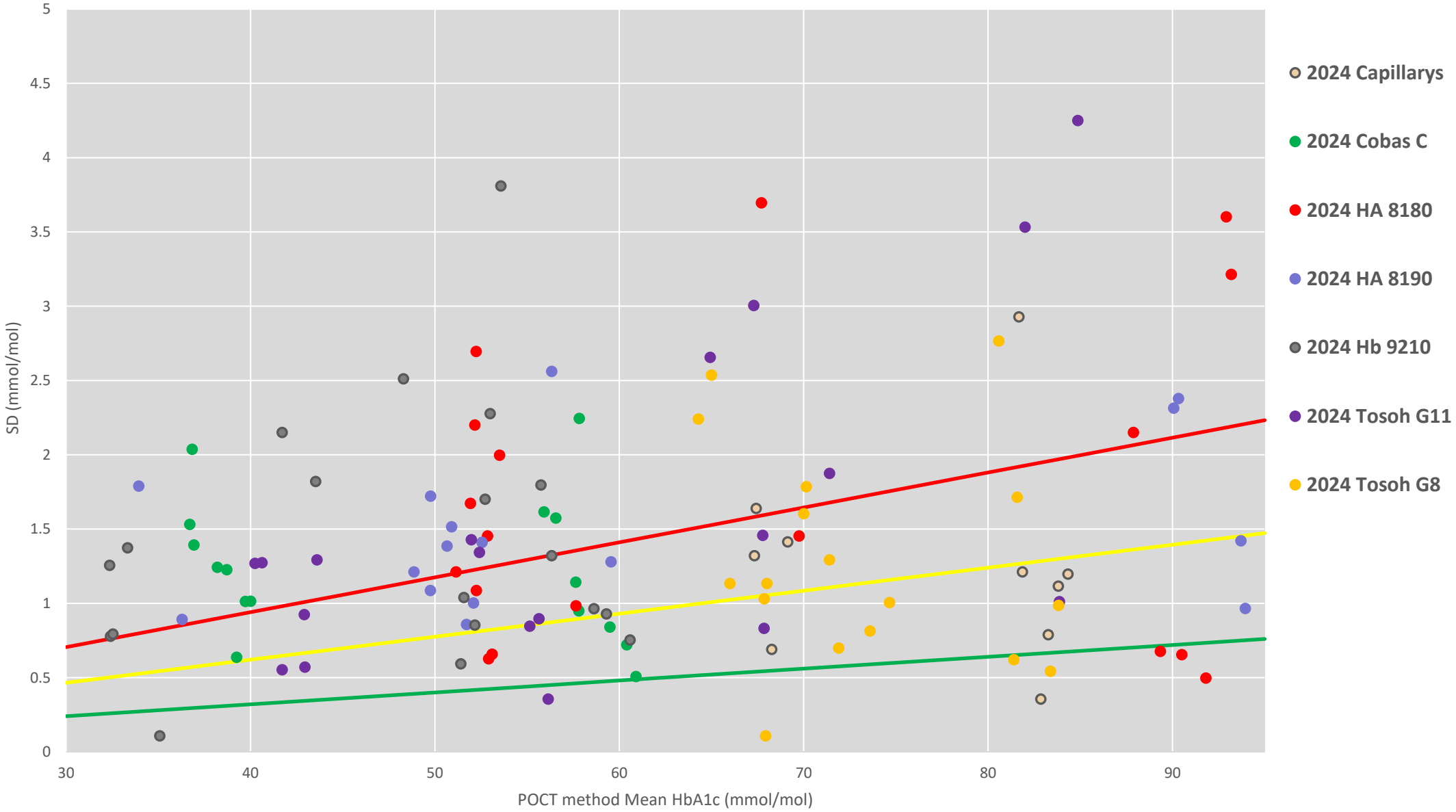


Can we use APS based on best lab method?

Laboratory Ion Exchange close to desirable



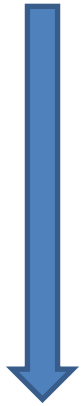
HbA1c Precision Profile, Lab Methods, SD mmol/mol



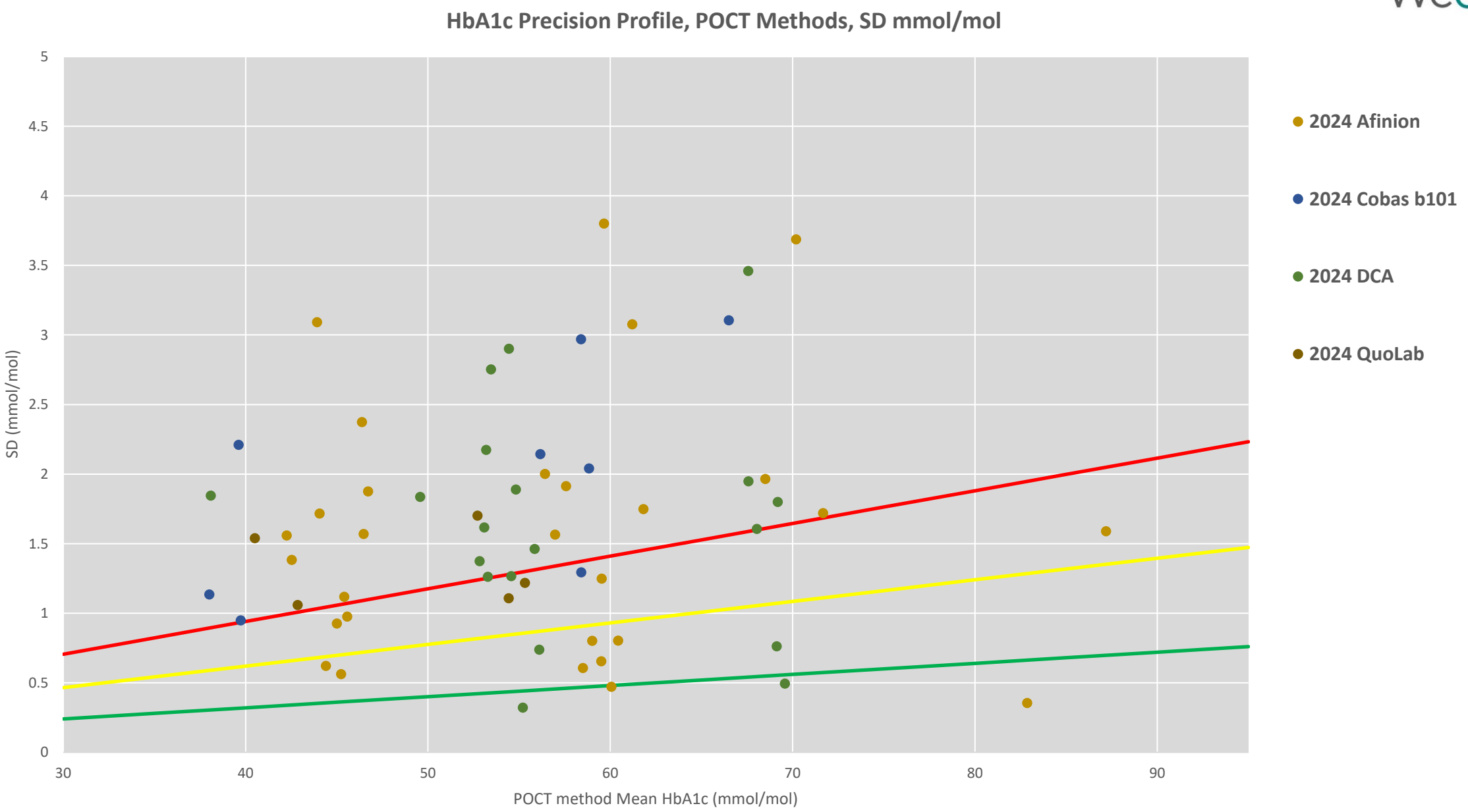
Weqas

Analytical performance specification of Test related to disease process

- Specification should be designed to provide performance assessment that best meets the needs of the service.
- What laboratory service is being provided?
  - Diagnosis
  - Prognosis
  - Monitoring
  - Screening



Performance specification may be different for the same analyte used in different settings


HbA1c Precision Profile, POCT Methods, SD mmol/mol
SD (mmol/mol)
POCT method Mean HbA1c (mmol/mol)
0
0.5
1
1.5
2
2.5
3
3.5
4
4.5
5
30
40
50
60
70
80
90
2024 Afinion
2024 Cobas b101
2024 DCA
2024 QuoLab

Weqas

Strategy for HbA1c

- Monitoring - Need method that is stable over time. Monitor intralaboratory variation as well as interlaboratory variation.

- Diagnosis - Need to ensure that WHO global target goals are valid. Monitor bias of method (lab performance) to standardised procedure (IFCC method).

WHO Recommendation

HbA1c can be used as a diagnostic test for diabetes providing that stringent quality assurance tests are in place and assays are standardised to criteria aligned to the international reference values, and there are no conditions present which preclude its accurate measurement.

An HbA1c of 48 mmol/mol (6.5%) is recommended as the cut point for diagnosing diabetes. A value of less than 48 mmol/mol does not exclude diabetes diagnosed using glucose tests.

APS based on Biological variation

	Intervention target	TEa (%)			Proposed APS
Analyte	Conc.	Min	Des	Opt	TEa (%)
Na	135 mmol/L	0.9	0.6	0.3	1.0 hybrid (best method)
K	3.5 mmol/L	7.3	4.9	2.4	Hybrid (2.4 opt + 4.9 des)
Ca	2.2 mmol/L	3.4	2.3	1.1	3.4 min
Creat	90 µmol/L	11.7	7.8	3.9	7.8 des
Glucose	2.0 / 6.5 mmol/L	9.2	6.1	3.1	6.1 des
Urate	360 µmol/L	19	12.6	6.3	Hybrid (6.3 opt +12.6 des)
Cholesterol	5.0 mmol/L	12.5	8.3	4.2	8.3 des
HDL	1.0 mmol/L	14.9	9.9	5.0	9.9 des
HbA1c	48 mmol/mol	4.7	3.1	1.6	5.0 hybrid (min + best method)

Highlighted TEa where minimum Biological goals not achievable